

56 (previously presented). The vector according to claim 49, which is any DNA not encapsidated by viral proteins.

REMARKS

I. Status of the Claims

With entry of this amendment, claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 are pending in this application. Claims 1-3, 6, 8, 10, 12-13, 16, 18, 20, 22, 24, 26, 28, 30, 32, and 38 are cancelled. Claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 are rejected. Claims 34-37 are withdrawn.

The following rejections are pending:

- a. claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 are rejected under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter, (Office Action mailed January 4, 2006 ("Office Action"), pages 9-10);
- b. claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, (Office Action, pages 3-7);
- c. claims 4, 5, 21, 23, 27, 31, 33, 39-41, 49, 50, 52, and 54-56 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kuo et al., Development, 126: 4223-4234 (1999) ("Kuo") (Office Action, pages 7-9);
- d. claim 4 is rejected under 35 U.S.C. § 102 as allegedly being anticipated by Aihara, Y., GenBank Accession No. AF131884 ("Aihara") (Office Action, 10-12)

Solely to advance prosecution and without disclaimer of or prejudice to the subject matter recited therein, Applicants cancel claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39.

Claim 40 is amended to more particularly describe the subject matter of the invention. Support for “[a]n isolated polynucleotide comprising SEQ ID NO: 1 or a sequence having at least 93% identity to SEQ ID NO: 1, wherein said polynucleotide comprises at least 92 nucleotides 3’ to the transcription start position +1” of claim 40 may be found, for example, in the claims as-filed and in the specification at page 20-21, paragraphs 85-86 and page 21, paragraph 92.

The amendments introduce no new matter.

II. Claims Are Drawn to Statutory Subject Matter

The Examiner rejects claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 under 35 U.S.C. § 101, as allegedly being directed to non-statutory subject matter. Specifically, the Examiner alleges that the specification permits the claim term “polynucleotide” to encompass genomic DNA. Office Action, pages 9-10. Solely to advance prosecution and without disclaimer of or prejudice to the subject matter recited therein, Applicants amend claim 40 to recite “[a]n isolated polynucleotide” Accordingly, claim 40 and dependent claims 41-56 are not directed to non-statutory matter under 35 U.S.C. § 101. With the cancellation of claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39, the rejection of these claims under 35 U.S.C. § 101 is moot.

III. The Claims Are Supported by the Specification

The Examiner rejects claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor had possession of the claimed invention at the time the application was filed. Office Action, page 4. With the cancellation of claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39, the rejection of these claims under 35 U.S.C. § 112 is moot.

Regarding claims 40-56, the Examiner alleges that “[t]he specification as filed fails to adequately describe a polynucleotide sequence having at least 93% sequence identity to SEQ ID NO: 1 which retains the function of specifically inducing expression in cardiac cells in vivo of a gene which is operably linked to said polynucleotide.” Office Action, page 5. The Examiner further alleges that the “functional limitation itself is not sufficient to provide a structure/function relationship for meeting the written description requirement because it is not clear what structure the polynucleotide sequence having at least 93% sequence identity to SEQ ID NO: 1 would have by the recitation of the functionality alone” *Id.*

Applicants respectfully traverse. Claim 40 as written includes polynucleotides having sequences with “at least 93% identity to SEQ ID NO: 1.” Thus, claim 40 recites more than a functional limitation, but also includes a structural limitation. Moreover, SEQ ID NO: 1 is disclosed in the application and, as the Examiner admits, the “specification provides adequate written description for a polynucleotide comprising

SEQ ID NO: 1." Office Action, page 5. One skilled in the art would understand how to determine if a given sequence is 93% identical to the whole SEQ ID NO: 1. No particular secondary or tertiary structure is required to convey the understanding of what is claimed. Based on the primary structure (the sequence) alone, one skilled in the art would readily understand the metes and bounds of claim 40, thus demonstrating possession of the invention by Applicants.

Moreover, the Examiner argues that "in the absence of any teaching by way of structure or reference to active domains or regions, one of skill in the art could not immediately envision those polynucleotide sequences having at least 93% identity to SEQ ID NO:1 . . ." Office Action, pages 5-6. However, in addition to SEQ ID NO:1, Applicants also disclose the human sequence upstream of the CARP gene (SEQ ID NO:2). By comparing the sequences from the human and mouse genes using simple alignment techniques, one skilled in the art would know how to determine those sequences that are identical and, thus, conserved. Consequently, one skilled in the art would understand that those conserved domains are "domains or regions" important to the function of the polypeptide and, contrary to the Examiner's assertions, the sequence provides the comparison framework for one skilled in the art to envision polynucleotide sequences having at least 93% identity to SEQ ID NO:1.

Accordingly, Applicants request that the rejections of claim 40 and dependent claims 41-56 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. The Claims Are Not Anticipated

The Examiner rejects claim 4 under 35 U.S.C. § 102(b) as allegedly being anticipated by Aihara. Office Action, page 10. With the cancellation of claim 4, the rejection of this claim under 35 U.S.C. § 102(b) over Aihara is moot.

The Examiner rejects claims 4, 5, 7, 21, 23, 27, 31, 33, 39-41, 49, 50, 52, and 54-56 under 35 U.S.C. § 102(b) as allegedly being anticipated by Kuo. Office Action, at page 7. With the cancellation of claims 4, 5, 7, 9, 21, 23, 27, 31, 33 and 39, the rejection of these claims under 35 U.S.C. § 102(b) over Kuo is also moot.

Regarding claims 40, 41, 49, 50, 52, and 54-56, the Examiner alleges that “SEQ ID NO:1 of the instant invention consists of a portion of the sequence between -2266 and +92.” Office Action, page 8. This is incorrect. SEQ ID NO:1 does not consist of a **portion** of the specified range of nucleotides, it consists of the **entire** range of nucleotides between -2266 and +92. The Examiner further asserts that Kuo teaches “a portion of the sequence between -2500 and +47, relative to the start position +1 of the mouse CARP gene . . . [and] SEQ ID NO: 1 of the instant invention shares 100% identity with the p2.5Luc construct disclosed by Kuo et al. at -2266 and +47 of the mouse CARP gene” and thus, allegedly anticipates the instant application. *Id.*

Applicants disagree. Claim 40 is drawn to the entire polynucleotide described by SEQ ID NO: 1, not the fragment disclosed by Kuo. Thus, it is clear that SEQ ID NO:1 is not 100% identical to the fragment disclosed by Kuo, as the Examiner asserts. In fact, SEQ ID NO:1 contains 44 nucleotides (from +48 to +92 relative to the transcription start position) that are nowhere found in Kuo.

Solely to advance prosecution and without disclaimer of or prejudice to the subject matter recited therein, Applicants amend claim 40 to recite “[a]n isolated polynucleotide . . . wherein said polynucleotide comprises at least 92 nucleotides 3' to the transcription start position +1 . . .” No sequence disclosed by Kuo discloses or suggests inclusion of the sequence comprising at least 92 nucleotides 3' to the transcription start position +1. Thus, no sequence in Kuo comprises 92 nucleotides downstream from the transcription start site and that is at least 93% identical to the entirety of SEQ ID NO: 1. Thus, Kuo cannot anticipate the disclosed invention.

For the aforementioned reasons, Applicants request that the rejections of claims 4, 5, 7, 9, 11, 14, 15, 17, 19, 21, 23, 25, 27, 29, 31, 33, and 39-56 be withdrawn.

PATENT
Customer No. 22,852
Attorney Docket No. 08888.0530-00000

SUMMARY

In view of the above amendments and remarks, Applicants submit that this application is in condition for allowance. An early and favorable action is earnestly solicited.

Please grant any extensions of time required to enter this amendment and response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: March 28, 2006

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